Attachment 2

Exhibit 351

INFECTION CONTROL SURVEYOR WORKSHEET

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (*e.g.*, the staff person responsible for sterilization should answer the sterilization questions).

A minimum of one surgical procedure must be observed during the site visit, unless the ASC is a low volume ASC with no procedures scheduled during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases.

When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS 2567 when deficient practices are observed.

PART 1 - ASC CHARACTERISTICS

1) ASC name: _____

2) Address: _____

_____

State: _____

3) 10-digit CMS Certification Number: _____

4) What year did the ASC open for operation? _____

5) Please list date(s) of site visit: _____ (mm/dd/yyyy) to _____ (mm/dd/yyyy)

6) What was the date of the most recent previous federal (CMS) survey: _____ (mm/dd/yyyy)

7) Does the ASC participate in Medicare via accredited "deemed" status? 1 ☐ YES 2 ☐ NO

7a) If YES, by which CMS-recognized accreditation organization? (Check only ONE):

1 ☐ Accreditation Association for Ambulatory Health Care (AAAHC)
2 ☐ American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
3 ☐ American Osteopathic Association (AOA)
4 ☐ The Joint Commission (JC)

7b) If YES, according to the ASC, what was the date of the most recent accreditation survey?
_____ (mm/dd/yyyy)

8) What is the ownership of the facility?
1 ☐ Physician-owned
2 ☐ Hospital-owned
3 ☐ National corporation (including joint ventures with physicians)
4 ☐ Other (please specify) _____

9) What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC). **Check only ONE**:
1 ☐ Dental
2 ☐ Endoscopy
3 ☐ Ear/Nose/Throat
4 ☐ OB/Gyn
5 ☐ Ophthalmologic
6 ☐ Orthopedic
7 ☐ Pain
8 ☐ Plastic/reconstructive
9 ☐ Podiatry
10☐ Other (please specify): _____

10) What additional procedures are performed at the ASC (Check all that apply)?
1 ☐ Dental
2 ☐ Endoscopy
3 ☐ Ear/NoseThroat
4 ☐ OB/Gyn
5 ☐ Ophthalmologic
6 ☐ Orthopedic
7 ☐ Pain
8 ☐ Plastic/reconstructive
9 ☐ Podiatry
10 ☐ Other (please specify): _____

11) Who does the ASC perform procedures on? (**Check only ONE**):

1 ☐ Pediatric patients only
2 ☐ Adult patients only
3 ☐ Both pediatric and adult patients

12) What is the average number of procedures performed at the ASC **per month**? _____

13) How many Operating Rooms (including procedure rooms) does the ASC have?

Number of rooms: a ☐1 b ☐2 c ☐3 d ☐4 e ☐5 f ☐6 g ☐7 h ☐8 i ☐more than 8

Number actively maintained:

a ☐1 b ☐2 c ☐3 d ☐4 e ☐5 f ☐6 g ☐7 h ☐8 i ☐more than 8

14) Please indicate how the following services are provided (check all that apply):

Anesthesia	a ☐Contract b ☐ Employee c ☐ Other (please specify)_____
Environmental Cleaning	a ☐Contract b ☐ Employee c ☐ Other (please specify)_____
Linen	a ☐Contract b ☐ Employee c ☐ Other (please specify)_____
Nursing	a ☐Contract b ☐ Employee c ☐ Other (please specify)_____
Pharmacy	a ☐Contract b ☐ Employee c ☐ Other (please specify)_____
Sterilization/Reprocessing	a ☐Contract b ☐ Employee c ☐ Other (please specify)_____
Waste Management	a ☐Contract b ☐ Employee c ☐ Other (please specify)_____

INFECTION CONTROL PROGRAM

15) Does the ASC have an explicit infection control program? 1 ☐ YES 2 ☐ NO

*NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 **must** be cited.*

16) Does the ASC's infection control program follow nationally recognized infection control guidelines?

1 ☐ YES 2 ☐ NO

*NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) **must** be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.*

16a) Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program?

1 ☐ YES 2 ☐ NO

16b) Which nationally-recognized infection control guidelines has the ASC selected for its program (Check all that apply)?

1 ☐ CDC /HICPAC Guidelines:
- a ☐ Guideline for Isolation Precautions (CDC/HICPAC)
- b ☐ Hand hygiene (CDC/HICPAC)
- c ☐ Disinfection and Sterilization in Healthcare Facilities (CDC/HICPAC)
- d ☐ Environmental Infection Control in Healthcare Facilities (CDC/HICPAC)

2 ☐ Perioperative Standards and Recommended Practices (AORN)
3 ☐ Guidelines issued by a specialty surgical society/organization (List)
_____
_____
_____
4 ☐ Others (please specify) _____
_____
_____
_____

*NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) **must** be cited. This is the case even if the ASC's*

infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51

17) Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program?

1 ☐ YES 2 ☐ NO

NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) ***must*** *be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.*

If YES,

17a) is this person an: (check only ONE):

1 ☐ ASC employee
2 ☐ ASC contractor_____

17b) Is this person certified in infection control (i.e., CIC) (Note: §416.50(b)(1) does *not* require that the individual be certified in infection control.)

1 ☐YES 2 ☐ NO

17c) If this person is **NOT** certified in infection control, what type of infection control training has this person received? _____

17d) On average how many hours per week does this person spend in the ASC directing the infection control program? (Note: §416.51(b)(1) does *not* specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)

_____

18) Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC? 1 ☐ YES 2 ☐ NO

18a) If YES, how does the ASC obtain this information? (Check ALL that apply)

1 ☐ The ASC sends e-mails to patients after discharge
2 ☐ The ASC follows-up with their patients' primary care providers after discharge
3 ☐ The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC
4 ☐ Other (please specify): _____

18b) Is there supporting documentation confirming this tracking activity?

1 ☐ YES 2 ☐ NO

*NOTE! If the ASC does not have an identification system, a deficiency related to 42 CFR 416.44(a)(3) and 42 CFR 416.51(b)(3) **must** be cited.*

18c) Does the ASC have a policy/procedure in place to comply with State notifiable disease reporting requirements?

1 ☐ YES 2 ☐ NO

*NOTE! If the ASC does not have a reporting system, a deficiency **must** be cited related to 42 CFR 416.44(a)(3). CMS does not specify the means for reporting; generally this would be done by the State health agency.*

19) Do staff members receive infection control training? 1 ☐ YES 2 ☐ NO

If YES,

19a) How do they receive infection control training (check all that apply)?

1 ☐ In-service
2 ☐ Computer-based training
3 ☐ Other (specify):_____

19b) Which staff members receive infection control training? (**check all that apply**):

1 ☐ Medical staff
2 ☐ Nursing staff
3 ☐ Other staff providing direct patient care
4 ☐ Staff responsible for on-site sterilization/high-level disinfection
5 ☐ Cleaning staff
6 ☐ Other (specify):_____

19c) Is training:

1 ☐ the same for all categories of staff
2 ☐ different for different categories of staff

19d) Indicate frequency of staff infection control training (check all that apply):

1 ☐ Upon hire
2 ☐ Annually
3 ☐ Periodically/as needed
4 ☐ Other (specify):_____

19d) Is there documentation confirming that training is provided to all categories of staff listed above?

1 ☐ YES 2 ☐ NO

*NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must** be cited in relation to 42 CFR 416.51(b)and (b)(3). If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice.*

20) How many procedures were observed during the site visit: a ☐1 b ☐2 c ☐3 d ☐4 e ☐Other

If other, please specify the number:_____

PART 2 – INFECTION CONTROL & RELATED PRACTICES

Instructions:

- Circle the applicable response, as well as information on the manner in which information was obtained
- Unless otherwise indicated, a "No" response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).
- If N/A is circled, please explain why there is no associated observation, or why the question is not applicable

I. Hand Hygiene

Additional Instructions:

- **Observations are to focus on staff directly involved in patient care (e.g., physicians, nurses, CRNAs, etc.).** Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey. Interviews are used primarily to provide additional evidence for what the surveyor has observed, but may in some cases substitute for direct observation to support a citation of deficient practice.

Practices to be Assessed	**Was practice performed?**	**Manner of confirmation**
A. All patient care areas have: Note: 42 CFR 416.51(a) should be cited only if the answer to both a and b is "No."		
a. Soap and water available	1 Yes 2 No	4Observation 5Interview 6Both
b. Alcohol-based hand rubs available	1 Yes 2 No	4Observation 5Interview 6Both
I. If alcohol-based hand rub is available in patient care areas, it is installed as required	1 Yes 2 No	**There are LSC requirements at 42 CFR 416.44(b)(5) for installation of alcohol-based hand rubs**
B. Staff perform hand hygiene:		
a. After removing gloves	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
b. After direct patient contact	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
c. Before performing invasive procedures (e.g., placing an IV)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
d. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

C. Regarding gloves, staff: a. Wear gloves for procedures that might involve contact with blood or body fluids	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
b. Wear gloves when handling potentially contaminated patient equipment	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
c. Remove gloves before moving to the next task and/or patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
D. Additional breaches in hand hygiene, not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
Comments:		

II. Injection Practices (injectable medications, saline, other infusates)

Additional Instructions:

Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

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Practices to be Assessed	**Was practice performed?**	**Manner of confirmation**
A. Needles are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
B. Syringes are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
C. Medication vials are always entered with a new needle	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
D. Medication vials are always entered with a new syringe	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
E.. Medications that are pre-drawn are labeled with the time of draw, initials of the person drawing, medication name, strength, and expiration date or time Note: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

F. a. Single dose (single-use) medication vials are used for only one patient (A "No" response must be cited in relation to 42 CFR 416.48(a).)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
b. Manufactured prefilled syringes are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
c. Bags of IV solution are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
d. Medication administration tubing and connectors are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

G. List all injectable medications/infusates that are in a vial/container used for **more than one patient:**

Name of Medication	Average number of patients per vial/container

H. Multi-dose injectable medications are used for only one patient (Note: a "No" answer here is not necessarily a breach in infection control and does not result in a citation. However, a "No" response to the related questions I – K should be cited. *Circle N/A if no multi-dose medications/infusates are used.*) **If YES, please skip to "L"**	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
If NO, please answer "I-K": I. The rubber septum on a multi-dose vial **used for more than one patient** is disinfected with alcohol prior to each entry	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

J. Multi-dose medications **used for more than one patient** are dated when they are first opened and discarded within 28 days of opening or according to manufacturer's recommendations, whichever comes first	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
K. Multi-dose medications, **used for more than one patient**, are not stored or accessed in the immediate areas where direct patient contact occurs	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
L. All sharps are disposed of in a puncture-resistant sharps container	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
M. Sharps containers are replaced when the fill line is reached	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
N. Additional breaches in injection practices, not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
Comments:		

III. Single Use Devices, Sterilization, and High-level Disinfection

Additional instructions:

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff who perform equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

SINGLE-USE DEVICES		
Practices to be Assessed	**Was practice performed?**	**Manner of confirmation**
A. If single-use devices are reprocessed, they are devices that are: a. Approved by the FDA for reprocessing b. Reprocessed by an FDA-approved reprocessor. *(Choose N/A if single-use devices are never reprocessed and used again)* *(Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)*	1 Yes 2 No 3 N/A 1 Yes 2 No 3 N/A	4Observation 5Interview 6Both 4Observation 5Interview 6Both
STERILIZATION		
Practices to be Assessed	**Was practice performed?**	**Manner of confirmation**
A. Critical equipment is sterilized	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
B. Are sterilization procedures performed on-site? (**If NO, Skip to "F"**) *(A "No" answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.)* *(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)* **IF YES,** Please indicate method of sterilization, ☐ Steam autoclave ☐ Peracetic acid ☐ Other (specify): _____	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to sterilization	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
b. A chemical indicator is placed in each load	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
c. A biologic indicator is performed at least weekly and with all implantable loads	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
d. Each load is monitored with mechanical indicators (e.g., time, temperature, pressure)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
H. Additional breaches in sterilization practices, not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
Comments:		

HIGH-LEVEL DISINFECTION		
Practices to be Assessed	**Was practice performed?**	**Manner of confirmation**
A. Semi-critical equipment is high-level disinfected or sterilized	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
B. Is high-level disinfection performed on-site? (**If NO, Skip to "F"**) *(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)* *(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)* **If YES,** Please indicate method of high-level disinfection, 1 ☐ Manual 2 ☐ Automated 3 ☐ Other (specify): _____	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both 4Observation 5Interview 6Both
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to high-level disinfection	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
b. High-level disinfection equipment is maintained according to manufacturer instructions	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
c. Chemicals used for high-level disinfection are:		
I. Prepared according to manufacturer instructions	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
II. Tested for appropriate concentration according to manufacturer's instructions	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
III. Replaced according to manufacturer's instructions	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
IV. Documented to have been prepared and replaced according to manufacturer's instructions	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
d. Instruments requiring high-level disinfection are:		
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or evidence-based guidelines	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions or evidence-based guidelines	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
E. Items that undergo high-level disinfection are allowed to dry before use	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
F. Following high-level disinfection, items are stored in a designated clean area in a manner to prevent contamination	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
G. Additional breaches in high level disinfection practices, not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

Comments:

IV. Environmental Infection Control

Additional Instructions:

Observations are to be made of staff who perform environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)

Practices to be Assessed	**Was practice performed?**	**Manner of confirmation**
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
B. Operating rooms are terminally cleaned daily	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
C. High-touch surfaces in patient care areas are cleaned and disinfected with an EPA-registered disinfectant	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
D. The ASC has a procedure in place to decontaminate gross spills of blood	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
E. Additional breaches in environmental cleaning not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

Comments:

V. Point of Care Devices (e.g., blood glucose meter)

Additional instructions:

Observations are to be made of staff who perform fingerstick testing (e.g., nurses)

If N/A is circled, please clarify why it was not applicable or not observed.

Practices to be Assessed	**Was practice performed?**	**Manner of confirmation**
Does the ASC have a blood glucose meter? 1Yes___ 2 No___ (**If NO, STOP HERE**)		
A. A new single-use, auto-disabling lancing device is used for each patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
B. The glucose meter is not used on more than one patient unless the manufacturer's instructions indicate this is permissible.	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
C. The glucose meter is cleaned and disinfected after every use.	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
D. Additional breaches in appropriate use of point of care devices (like glucose meters) not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
Comments:		